DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

November 20, 2014

St. Jude Medical
Zachary Price
Regulatory Affairs Specialist
15900 Valley View Court
Sylmar, CA 91342

Re: K142254
Trade/Device Name: CPS Excel MediGuide Enabled Guidewire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: November 13, 2014
Received: November 13, 2014

Dear Mr. Price:

This letter corrects our substantially equivalent letter of November 13, 2014.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Melissa A. Torres -S

For Bram Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142254

Device Name
CPS Excel™ MediGuide Enabled™ Guidewire Models DS2M027, DS2M028, DS2M029

Indications for Use *(Describe)*
The St. Jude Medical CPS Excel™ MediGuide Enabled™Guidewire is intended for use with the MediGuide™ System to enable real-time tip positioning and navigation within the coronary and peripheral vasculature (such as to facilitate left heart lead implantation). The MediGuide system is intended for use as an adjunct to fluoroscopy.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(K) SUMMARY

510(k) Summary

The purpose of this special 510(K) is to gain clearance for the CPS Excel™ MediGuide Enabled™ Guidewire Models DS2M027, DS2M028, DS2M029 and accessories. There are no design changes to the Guidewire Models DS2M027, DS2M028, and DS2M029. The design features of the CPS Excel™ MediGuide Enabled™ Guidewire Connector accessory DS2M033 have only undergone minimal design changes to connect directly to the MediGuide technology as compared to the predicate, MediGuide Enabled™ Guidewire Connector DS2M032 (K120298).

Submitter:	St. Jude Medical, CRMD
Address:	15900 Valley View Ct Sylmar, CA 91342
Phone: Fax:	818 493 2903 818 493 3615
Contact Person:	Zachary Price

Trade Name/Proprietary Name:	CPS Excel™ MediGuide Enabled™ Guidewire and accessories
Common Name:	Catheter, Guidewire Model Numbers: DS2M027, DS2M028, DS2M029, DS2M030, DS2M033
Legally marketed device to which your firm is claiming equivalence:	CPS Excel™ MediGuide Enabled™ Guidewire and accessories (K120298)

Device Description:

The device description of the CPS Excel™ MediGuide Enabled™ Guidewire Connector accessory DS2M033 is as follows.

The Connector accessory is a flexible, insulated cable that is used to connect the CPS Excel™ MediGuide Enabled™ guidewire to the MediGuide Technology. The guidewire is inserted into the connector until it bottoms out. Once the guidewire cannot be pushed any further, the nut on the connector end is tightened to fixate the guidewire in the connector. Inside the molded connector housing is a printed circuit board (PCB) which is wrapped with magnetic shielding. The PCB has contact slots that connect with the electrical contacts of the guidewire for electrical functionality. The other end of the MediGuide guidewire connector is a ODU-compatible connector that connects to the MediGuide Technology catheter connect box.

The indication for use is as follows:

The St. Jude Medical CPS Excel™ MediGuide Enabled™ Guidewire is intended for use with the MediGuide™ System to enable real-time tip positioning and navigation within the coronary and peripheral vasculature (such as to facilitate left heart lead implantation). The MediGuide system is intended for use as an adjunct to fluoroscopy.

Technological Characteristics of the Device Compared to the Predicate Device:

The device has the same technological characteristics as the currently marketed CPS Excel™ MediGuide Enabled™ Guidewire connector, with only minimal changes to the cable length, connector type, connector construction to accommodate change to connect directly to the MediGuide Technology

Non-clinical Test Summary:

The risk analysis method used to assess the impact of the modification of the CPS Excel™ MediGuide Enabled™ Guidewire Connector accessory DS2M033 documents the investigation of hazards and the mitigation of risks associated with its use and reports the results of the investigation. The risk analysis method used to assess the impact of the modifications was a Failure Modes and Effects Analysis (FMEA/FMECA). It was determined that overall residual risk is acceptable.

Verification and validation testing of the Connector accessory included the following testing and associated guiding standards: (1) bubble leak testing (ASTM F2096), (2) peel testing for seal strength (ASTM F88), (3) visual inspection testing (ISO 10555-1:2009), (4) dimensional testing (ISO 11070:1999), (5) cable joint flex testing (ANSI/AAMI EC53:1995/º2008), and (6) label testing (BS EN-45502-1). Successful completion of all verification and validation activities, (as shown in Table 4) demonstrated that the candidate devices meet their predetermined design and performance specifications and that the products are substantially equivalent to the predicate devices.

Conclusion (Statement of Equivalence):

The results of the verification and validation tests and the risk analysis have demonstrated the CPS Excel™ MediGuide Enabled™ Guidewire and accessories functions in accordance with product specifications that were previously cleared for the predicate device, , the CPS Excel™ MediGuide Enabled™ Guidewire connector DS2M032 cleared in 510(k) K120298.

Therefore, St. Jude Medical considers the CPS Excel™ MediGuide Enabled™ Guidewire and accessories to be substantially equivalent to the legally marketed predicate device, the CPS Excel™ MediGuide Enabled™ Guidewire connector DS2M032 cleared in 510(k) K120298.